

Press Release

Montrouge, France, March 10, 2017

DBV Technologies Announces Completion of Enrollment of the REALISE Study in Peanut Allergic Children

Higher-than-expected patient demand leads to increased randomization target

Study includes patients with or without a history of severe anaphylaxis

Global Phase III program results expected in 2H 2017

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT) today announced that patient enrollment in the REALISE (REAL Life Use and Safety of EPIT) trial was completed. REALISE is the company's Phase III study designed to assess the safety and routine clinical use of Viaskin Peanut 250 µg for the treatment of peanut allergic children four to 11 years of age, including patients with a history of severe anaphylaxis. Viaskin Peanut is the company's lead product candidate, which is based on epicutaneous immunotherapy (EPIT), a proprietary technology platform that can deliver biologically active compounds to the immune system through the skin.

Enrollment in the REALISE study exceeded initial expectations. A total of 483 patients were screened, and the company increased its initial randomization target of 335 patients to approximately 394 patients. Topline results from the REALISE trial as well as the PEPITES trial, the company's pivotal Phase III safety and efficacy trial, are expected in the second half of 2017.

Dr. Jacqueline Pongracic, Head, Allergy and Immunology, Ann & Robert H. Lurie Children's Hospital of Chicago, Professor of Pediatrics and Medicine, Northwestern University Feinberg School of Medicine, and Principal Investigator of REALISE, said: *"We eagerly anticipate the results from this novel study, which is leading the way towards the advancement of treatment for peanut-allergic children. Importantly, we are pleased to see a study that includes patients with a history of severe anaphylaxis, a population that has historically been excluded from previous clinical trials, and represent a significant unmet clinical need."*

"The high level of interest from patients and the rapid completion of enrollment in REALISE further highlight the need for a treatment of this potentially life-threatening condition," said **Dr. Lucia Septián**, Chief Medical Officer of DBV Technologies. *"Following the successful enrollment in PEPITES, we are pleased to see continued excitement from patients, caregivers, and clinicians, and would like to thank them for their participation and support in our trials."*

[About the REALISE Study](#)



REALISE is a multicenter, randomized, double-blind, placebo-controlled Phase III study designed to assess the use of Viaskin Peanut 250 µg in routine medical practice and generate safety data after six months of blinded treatment in patients four to 11 years of age. At the six-month time point, patients in both the placebo and active arms will be able to opt into an open-label portion of the study, which will continue monitoring patients for a total of 36 months of active treatment. Exploratory criteria will also include scores from patients' Food Allergy Quality of Life Questionnaire (FAQLQ) and the Food Allergy Independent Measure (FAIM), as well as the evolution of peanut-specific serological markers over time. The study is being conducted in 32 centers in North America. No oral food challenges are required in REALISE. Patients in the study will be selected based on a well-documented medical history of IgE-mediated reactions to peanut, including children with a history of severe anaphylaxis, as well as analyses of baseline peanut-specific immunological markers. During the first six months of trial, patients will be randomized 3:1 active versus placebo. Key assessments of safety parameters will include treatment-emergent adverse events observed in both the placebo and active treatment groups during the initial six months, which will continue to be monitored during the open-label portion of the study. DBV intends to randomize approximately 394 patients in REALISE.

About the PEPITES Study

The Peanut EPIT Efficacy and Safety Study (PEPITES) is a global, pivotal, double-blinded, placebo-controlled Phase III trial designed to evaluate the safety and efficacy of Viaskin Peanut 250 µg in children ages four to 11 years. During PEPITES, patients' response will be assessed using a double-blind, placebo controlled food challenge (DBPCFC). Patients are randomized 2:1 to receive either Viaskin Peanut 250 µg or placebo for 12 months. The primary endpoint is based on a responder analysis after 12 months of treatment with Viaskin Peanut 250 µg. For patients with a baseline peanut protein eliciting dose (ED) equal to or less than 10 mg, a responder is defined as a patient with a peanut protein ED equal to or greater than 300 mg of peanut protein after 12 months of treatment. For patients with a baseline ED greater than 10 mg, a responder is defined as a patient with a peanut protein ED equal to or greater than 1,000 mg of peanut protein after 12 months of treatment. As a secondary efficacy endpoint, Cumulative Reactive Dose (CRD), will also be used in PEPITES to establish the total quantity of peanut protein that triggers patient reactions at month 12 of active treatment versus placebo. Serological markers will also be measured at baseline, 3, 6, and 12 months in order to characterize the immunological changes in patients.

Following the completion of PEPITES, all patients are eligible to rollover into PEOPLE, a long-term, open-label extension study of Viaskin Peanut 250 µg. In the PEOPLE study, patients who were randomized to active treatment during PEPITES will receive Viaskin Peanut 250 µg for two additional years; patients who were previously receiving placebo during PEPITES will be treated with Viaskin Peanut 250 µg for three years. Patients enrolling in the PEOPLE study will remain blinded to their respective treatment group in PEPITES until the PEPITES study results become publicly available.

About DBV Technologies

DBV Technologies is developing Viaskin®, a proprietary technology platform with broad potential applications in immunotherapy. Viaskin is based on epicutaneous immunotherapy, or EPIT®, DBV's method of delivering biologically active compounds to the immune system through intact skin. With this new class of self-administered and non-invasive product candidates, the company is dedicated to safely transforming the care of food allergic patients, for whom there are no approved treatments. DBV's food allergies programs include ongoing clinical trials of Viaskin Peanut and Viaskin Milk, and preclinical development of Viaskin Egg. DBV is also pursuing a human proof-of-concept clinical study of Viaskin Milk for the treatment of Eosinophilic Esophagitis, and exploring potential applications of its platform in vaccines and other immune diseases.

DBV Technologies has global headquarters in Montrouge, France and New York, NY. Company shares are traded on segment A of Euronext Paris (Ticker: DBV, ISIN code: FR0010417345), part of the SBF120 index, and traded on the Nasdaq Global Select Market in the form of American Depositary Shares (each representing one-half of one ordinary share) (Ticker: DBVT). For more information on DBV Technologies, please visit our website: www.dbv-technologies.com

Forward Looking Statements



This press release may contain forward-looking statements and estimates, including statements regarding the potential safety and efficacy of Viaskin Peanut, statements regarding the anticipated timing of data from clinical trials and statements reflecting management's expectations for clinical development of our product candidates and the commercial potential of our product candidates. These forward-looking statements and estimates are not promises or guarantees and involve substantial risks and uncertainties. At this stage, the products of the Company have not been authorized for sale in any country. Among the factors that could cause actual results to differ materially from those described or projected herein include uncertainties associated generally with research and development, clinical trials and related regulatory reviews and approvals, the risk that historical preclinical results may not be predictive of future clinical trial results, and the risk that historical clinical trial results may not be predictive of future trial results. A further list and description of these risks, uncertainties and other risks can be found in the Company's regulatory filings with the French Autorité des Marchés Financiers, the Company's Securities and Exchange Commission filings and reports, including in the Company's Annual Report on Form 20-F for the year ended December 31, 2015 and future filings and reports by the Company. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements and estimates, which speak only as of the date hereof. Other than as required by applicable law, DBV Technologies undertakes no obligation to update or revise the information contained in this Press Release.

DBV Technologies Contact

Susanna Mesa

Senior Vice President, Strategy

+1 212-271-0861

susanna.mesa@dbv-technologies.com

Media Contact

Andrea Fassacesia, Weber Shandwick

+1 212-445-8144

afassacesia@webershandwick.com

Media Contact Europe

Caroline Carmagnol, Alize RP, Relations Presse

+33 (0)6 64 18 99 59

caroline@alizerp.com